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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/571,018	03/08/2006	Mikio Shoji	023312-0122	4736

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EXAMINER	
EMCH, GREGORY S	

ART UNIT	PAPER NUMBER
1649	

MAIL DATE	DELIVERY MODE
11/13/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/571,018	SHOJI ET AL.	
	Examiner	Art Unit	
	Gregory S. Emch	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 August 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *23-43* is/are pending in the application.

4a) Of the above claim(s) *43* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

Claims 23 and 24 have been amended as requested in the amendment filed on 03 August 2009. Following the amendment, claims 23-43 are pending in the instant application,

Claim 43 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the replies filed on 10 July 2008 and 20 November 2008.

Claims 23-42 are under examination in the instant office action.

Claim Rejections Withdrawn

The rejection of claims 23-42 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in response to the amendment to independent claim 23 that clarifies the scope of the claimed derivative.

The rejection of claims 23-42 under 35 U.S.C. 112, first paragraph, for scope of enablement is withdrawn in response to the amendment to claims 23 and 24 to delete "preventing."

Applicant's arguments, see pp.7-8 of the Remarks filed on 03 August 2009, with respect to the rejection(s) of claim(s) 23, 24, 26, 27, 29, 30, 32, 36, 37 and 39-41 under 35 U.S.C. 102(b) as being anticipated by Suzuki et al. (US Patent no. 5,750,349) have

been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made as set forth below.

Duplicate Claims, Warning

Applicant is advised that should claim 28 be found allowable, claim 33 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 34 and 35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it

The invention appears to employ novel biological materials, specifically the BA-27a and BC-05a antibodies. Since the biological materials are essential to the claimed

invention they must be obtainable by a repeatable method set forth in the specification or otherwise readily available to the public. It appears that applicants have deposited the biological materials at a depository recognized under the Budapest Treaty (p.5, line 34 – p.6, line 14 of the specification). Accordingly, an affidavit or declaration by applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the specific biological materials have been deposited under the Budapest Treaty and that the biological materials will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, and that the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer, would satisfy the deposit requirement made herein.

Applicants' attention is directed to M.P.E.P. §2400 in general, and specifically to §2411.05, as well as to 37 C.F.R. § 1.809(d).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 23-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schenk et al. (WO 00/72880A2, published 07 December 2000), in view of Suzuki et al. (5,750,349; issued 12 May 1998; citation A1 from IDS dated 08 March 2006).

Schenk (WO 00/72880A2) discloses methods of treating a disease characterized by amyloid deposits of amyloid-beta (Aβ) in the brain of a patient (including Alzheimer's disease, Down's syndrome and cognitive impairment in human patients), comprising either active immunization methods or passive immunization methods. Active immunization is practiced via administration to a subject of an effective amount of an immunogenic Aβ peptide, including Aβ 35-42, such that antibodies to the peptide are generated in the subject (see e.g. p.27, lines 26-31). Passive immunization is practiced via administration to a subject of an effective amount of an antibody to an Aβ peptide

(see e.g. p.32, lines 20-27). Schenk teaches the desirability of administration of an effective dosage of antibodies that specifically bind to a component of an amyloid deposit in the patient (p.2, lines 28-33; p.11, line 24). Some of the antibodies bind to the long form of Aβ (i.e. Aβ 1-42 or Aβ 1-43), while not binding to a short form of Aβ (i.e. Aβ 1-39, Aβ 1-40 or Aβ 1-41)(see p.33, lines 24-26), thus implying the suitability of C-terminal antibodies to Aβ 1-42 or Aβ 1-43 for treatment of Alzheimer's disease. Schenk does not explicitly teach administration of an antibody that specifically reacts with a partial peptide at the C-terminal region of Aβ but does not recognize a partial peptide of SEQ ID NO: 8, as claimed.

However, the Suzuki patent teaches the specific monoclonal antibodies which are administered in the instant method claims. It is noted that Suzuki's SEQ ID NOs: 1, 2, 3, 4, 5, 6, 7, 8 and 9 are identical to the instant SEQ ID NOs: 1, 2, 3, 4, 5, 6, 7, 8 and 9, respectively. Thus, Suzuki teaches the antibody of claims 23-25 at col.4, lines 50-55. The antibody of claim 26 is taught at col.4, lines 60-65. The antibody of claims 27, 28 and 33 is taught at col.5, lines 47-50. The antibody of claim 29 is taught at col.5, lines 51-61. The patent teaches antibodies to derivatives which meet the limitations recited by claims 23 and 30 at col.5, lines 62-65 and which meet the limitations recited by claim 31 at col.6, lines 1-3. The antibody of claim 32 is taught at col.6, lines 4-6. The antibody of claim 34 (i.e. BA-27a) is taught at col.6, lines 64-65 and the antibody of claim 35 (i.e. BC-05a) is taught at col.7, lines 1-2. The antibody of claim 42 is taught at col.6, lines 50-61. It is noted that the limitations of claims 36-41 recite properties or effects of the antibodies upon administration to humans which are inherent to the

antibodies. Since the Suzuki patent teaches the structural requirements of the antibodies encompassed by the claims, the functional limitations of the antibodies of claims 36-41 are taught. The patent also teaches that the antibodies of the invention are useful for the development of preventative or therapeutic compositions for Alzheimer's disease (abstract). Suzuki does not explicitly teach administration of the antibodies for methods of treating Alzheimer's disease.

However, it would have been *prima facie* obvious to the person of ordinary skill in the art at the time the invention was made to modify the methods of Schenk as taught by Suzuki et al. to yield predictable results. As evidenced by the Schenk document, the artisan of ordinary skill would have known that an antibody specific to the long form of Aβ (i.e. Aβ 1-42 or Aβ 1-43) would be useful in treating Alzheimer's disease and/or cognitive impairment. As evidenced by Suzuki et al., the artisan of ordinary skill would have known that the C-terminal antibodies disclosed therein could be used in methods of developing treatments for Alzheimer's disease. Furthermore, it would have been reasonable to predict that the antibodies of Suzuki could be successfully used in the methods of treating Alzheimer's disease and/or cognitive impairment taught by Schenk because Schenk suggests that such antibodies would be suitable. That is, given that Schenk teaches that raising antibodies against the long form of Aβ would be desirable and teaches that a preferred immunogenic peptide is Aβ 35-42, and given that Suzuki et al. teach such C-terminal antibodies against the long form of Aβ, the artisan of ordinary skill would have found it obvious to try to use Suzuki's antibodies in Schenk's treatment methods. Therefore, it would have been *prima facie* obvious to the person of ordinary

skill in the art at the time the invention was made to modify Schenk's treatment methods by administering Suzuki's antibodies to yield predictable results. This is because the artisan has good reason to pursue the known options within his or her technical grasp to obtain predictable results. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense.

Conclusion

No claims are allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. DeMattos et al. (PNAS 2001; Citation A6 on IDS dated 08 March 2006) indicates that administration of antibodies against Aβ is sufficient to treat the disease and that administration leads to Aβ going from the brain to the circulation, without the antibody entering the brain.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gregory S. Emch whose telephone number is (571) 272-8149. The examiner can normally be reached 9:00 am - 5:30 pm EST (M-F).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey J. Stucker can be reached at (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/G.E./

Gregory S. Emch
Patent Examiner
Art Unit 1649
08 November 2009

/Daniel E. Kolker/
Primary Examiner, Art Unit 1649
November 9, 2009